FEB 21 2002

K013241

Safety and Effectiveness Information

Submitted by: Heidi Masten
Regulatory Affairs Coordinator
COOK INCORPORATED
750 Daniels Way
P.O. Box 489
Bloomington, IN 47402-0489
812-339-2235

Device:	Trade Name:	Arndt Cricothyroid Catheter Set
	Proposed Classification:	Emergency Airway Needle
Predicate Devices:	Melker Cuffed Cricothyroid Catheter	Marketed & Distributed by Cook Inc. (K010016)
	The Pertrach	Marketed and Distributed by Pertrach Inc. (K914743)

Device Description:

The Arndt Cricothyroid Catheter consists of a connector on the proximal end connected to tubing with an inner diameter. Through the catheter lumen is a dilator. The dilator provides a transition to a wire guide for insertion. The device is placed using the Seldinger technique. The catheter will be included in a set consisting of appropriately sized components.

Indications for Use:

The Arndt Cricothyroid Catheter is used for emergency airway access when conventional endotracheal intubation cannot be performed. It is provided in peel-open packages and is intended for one-time use.

Substantial Equivalence:

The Arndt Cricothyrotomy Catheter is similar in design and intended use to two legally marketed devices including: The Melker Cuffed Cricothyrotomy Catheter Set, manufactured by Cook Inc. and the Pertrach, manufactured by Pertrach Inc.

These devices are used for airway access, have similar technical characteristics and are made of similar materials.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 21 2002

Ms. Heidi Masten
Cook Incorporated
P.O. Box 489
Bloomington, IN 47402-0489

Re: K013241
Arndt Emergency Cricothyrotomy Catheter Set
Regulation Number: 868.5090, 868.5800
Regulation Name: Emergency Airway Needle, Tracheostomy Tube and Tube Cuff
Regulatory Class: II (two)
Product Code: 73 BWC, 73 BTO
Dated: December 21, 2001
Received: December 26, 2001

Dear Ms. Masten:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

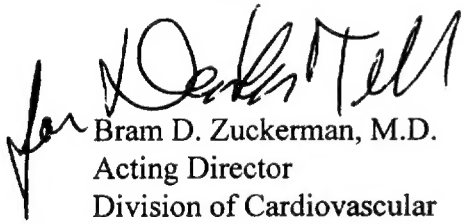
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration (21 CFR Part 807); listing (21 CFR Part 807), labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market. If you desire specific advice for your device on the labeling regulation (21 CFR Part 801 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

Device Name Arndt Emergency Cricothyrotomy Catheter Set

Indications for Use:

- Used for emergency airway access when conventional endotracheal intubation and ventilation cannot be performed.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

_____ _____ _____ _____ _____ _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K013594

Prescription Use √ OR Over-the-Counter Use_____
(Per 21 CFR 801.109)